

REMARKS

It is respectfully requested that this application be reconsidered in view of the above amendment and the following remarks and that all of the claims remaining be allowed.

Claim Amendments

Claim 1 has been amended to recite "each selected from...", for which support can be found, for example, at page 8, lines 7-9.

No new matter has been added by these amendments. The Examiner is hereby requested to enter these amendments.

Request for Continued Examination

Applicants hereby request continued examination of the present application under 37 C.F.R. §1.114.

Rejection Under 35 U.S.C. §103:

(a) Anderson in view of Yan

The rejection of claims 1-5 under 35 U.S.C. §103 over Anderson (U.S. Patent No. 6,242,213 B1) in view of Yan (U.S. Patent No. 5,856,928) is respectfully traversed for the reasons set forth below.

To properly issue a rejection under 35 U.S.C. §103, the USPTO bears the initial burden to establish a *prima facie* case of obviousness by meeting three criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to arrive at the claimed invention. *In re Vaeck*, 20 USPQ 2d 1438 (Fed. Cir. 1991). Second, there must be a reasonable expectation of success. *Id.* Finally, the prior art reference or the combination of references must teach or suggest all the claim limitations. *In re Royka*, 180 USPQ 580 (CCPA 1974).

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These criteria are not met in the instant case. Claim 1 is directed to a coiled-coil polypeptide composition, comprising a template of the form $(ab_i c_i d e_j f_j g_i)_n$, where $i=1,2,\dots,n$, and n is at least three, a and d are amino acids each selected from the group consisting of leucine, isoleucine, valine, phenylalanine, methionine, tyrosine, and derivatives thereof, and the sequence formed by the positions $(b_i c_i e_j f_j g_i)_n$ is a sequence of amino acids from a solvent-accessible region of an epitope from a selected protein, wherein said region is not in a coiled-coil conformation in its native state. Therefore, the claimed invention pertains to a coiled-coil polypeptide converted, using a coiled-coil template, from a protein region that is not in a coiled-coil conformation in its native state. Claims 2-5 depend from claim 1 and hence recite all the above claim elements.

Anderson teaches the sequence of and compositions comprising RANK-L, an immune regulator. In teaching the various fusion proteins comprising RANK-L, Anderson discloses that RANK-L may be fused with a leucine zipper domain (column 5), and that the leucine zipper domain forms a coiled-coil (column 6). Anderson does not teach or suggest changing any protein region that is not in a coiled-coil conformation in its native state into a coiled-coil polypeptide using a coiled-coil template.

The Yan reference teaches a numerical method for the analysis of sequence information of DNA, RNA and proteins. Thus, each kind of nucleotide base, base pairing and amino acid is assigned a number, and a DNA, RNA or protein can be represented, characterized and interpreted by sums of the numbers assigned to its constituent nucleotide, base pairing or amino acid. Many examples were used to illustrate this method. In one of the examples, the numerical sums were deduced for the prion proteins, and Yan concluded that prion proteins are fibrous chains like those in Type I collagen, silk fibroin, fibrinogen or tropomyosin (column 40, lines 47-48). Yan further discloses that most of these fibrous protein strands aggregate through hydrogen bond zippers (column 40, lines 49-50) and are gelling proteins which are either wound-healing or disease-causing agents (column 40, lines 58-59). Yan does not teach or suggest changing any protein region that is not in a coiled-

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coil conformation in its native state into a coiled-coil polypeptide using a coiled-coil template.

In view of the disclosure of Anderson and Yan, there is simply no suggestion or motivation to combine these two references and modify the reference teachings to arrive at the claimed invention. The Office Action states in the first paragraph of page 4:

It would have been *prima facie* obvious... to substitute and combine the composition (prion protein in this case)...of Yan in the polypeptide composition of Anderson, since Yan states, "The gelling proteins-fibrogen, beta amyloid, and prions- are either wound-healing or disease-causing agents (Column 40, lines 58-59)".

Applicants can not understand why the teaching that gelling proteins are wound-healing or disease-causing agents would constitute a motivation to convert the proteins to a coiled-coil protein as claimed in the instance application. An explanation is respectfully requested.

The Office Action further states, also in the first paragraph on page 4:

An ordinary practitioner would have been motivated to substitute and combine the composition (prion protein in this case), wherein the solvent-accessible region is not in a coiled-coil conformation in its native state of Yan in the polypeptide composition of Anderson in order to achieve the express advantages, as noted by Yan, of an invention that can detect gelling proteins- fibrogen, beta amyloid, and prions- which are either wound-healing or disease-causing agents.

This statement is equally confusing. Applicants assume the "express advantages" "noted by Yan" relate to the ability to detect gelling proteins. How are these advantages achieved by converting the gelling proteins to coiled-coil proteins, and where is it taught or suggested in the references? In this regard, Applicants wish to remind the Examiner that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP §2143.

Furthermore, combination of the two references does not offer a reasonable expectation of success, or teach or suggest all the claim elements. As discussed above,

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neither reference teaches, suggests, or even relates to changing a non-coiled-coil protein region into a coiled-coil using a coiled-coil template. Combining the references does not cure the deficiency.

Accordingly, this rejection does not satisfy the requirement under 35 U.S.C. §103, and its withdrawal is respectfully requested.

(b) Anderson in view of Yan further in view of Prusiner et al.

The rejection of claims 1-9 under 35 U.S.C. §103 over Anderson (U.S. Patent No. 6,242,213 B1) in view of Yan (U.S. Patent No. 5,856,928) and further in view of Prusiner et al. (U.S. Patent No. 5,792,901) is respectfully traversed for the reasons set forth below.

This rejection also fails to satisfy the three criteria set forth above as required under 35 U.S.C. §103. It has been discussed above that the claimed invention pertains to a coiled-coil polypeptide converted, using a coiled-coil template, from a protein region that is not in a coiled-coil conformation in its native state. It has been further discussed that Anderson and Yan, either alone or in combination, do not teach or suggest the claimed invention in any way. The Prusiner et al. reference fails to correct these deficiencies.

Prusiner et al. teach an artificial prion protein gene, transgenic animals harboring the prion protein gene, and certain methods of using the prion protein gene. The reference does not teach or suggest changing a protein region that is not in a coiled-coil conformation in its native state into a coiled-coil polypeptide. In fact, Prusiner et al. do not discuss the coiled-coil protein conformation at all. Therefore, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to arrive at the claimed invention. Nor is there a reasonable expectation of success. The three references, or the combination of references, also do not teach or suggest all the claim elements. Clearly, the requirement under 35 U.S.C. §103 is not met.

The Office Action points out that one object of the Prusiner reference is to provide a method of testing samples for the presence of prions. The Office Action then concludes on page 5 that

An ordinary practitioner would have been motivated to substitute and combine the epitopes present on the exposed surface regions of infectious prion protein of Prusiner et al. in the polypeptide composition of Anderson in view of Yan, in order to achieve the express advantages, as noted by Prusiner et al., of an invention that provides for a method of testing samples for the presence prions.

This statement is not supported by the relevant law. The prior art must suggest the desirability of the claimed invention, MPEP §2143.01 (emphasis added), not merely the desirability of the effect of the claimed invention. Here, one object of Prusiner et al. was to provide a method of testing samples for the presence of prions, and Prusiner et al. indeed teach a method of detecting prions, by using genetically altered animals (see, for example, column 6, lines 17-31 of Prusiner et al.). This method does not relate to coiled-coil proteins, let alone the claimed invention, which requires a coiled-coil polypeptide that is converted from a non-coiled-coil protein region. A mere wish to detect prions does not provide any suggestion to make the claimed composition. Absent such suggestion, there is no motivation to specifically combine Prusiner et al. with Anderson and/or Yan, rather than other references, or to modify the teachings to arrive at the claimed invention.

Accordingly, this rejection is improper, and Applicants respectfully request its withdrawal.

Conclusions:

For the reasons set forth above, Applicants submit that the claims of this application are patentable. Reconsideration and withdrawal of the Examiner's rejections are hereby requested. Allowance of the claims remaining in this application is earnestly solicited.

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In the event that a telephone conversation could expedite the prosecution of this application, the Examiner is requested to call the undersigned at (650) 622-2300.

Respectfully submitted,

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Attachment to RCE dated January 23, 2003

Marked-up Version
Claim 1

1. (Twice amended) A coiled-coil polypeptide composition, comprising a template of the form $(ab_i c_i d e f g_i)_n$, where $i=1,2,\dots,n$, and n is at least three, a and d are amino acids each selected from the group consisting of leucine, isoleucine, valine, phenylalanine, methionine, tyrosine, and derivatives thereof, and the sequence formed by the positions $(b_i c_i e f g_i)_n$ is a sequence of amino acids from a solvent-accessible region of an epitope from a selected protein, where said region is not in a coiled-coil conformation in its native state.

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